

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TALECRIS BIOTHERAPEUTICS, INC.,

Plaintiff,

v.

BAXTER INTERNATIONAL INC., and
BAXTER HEALTHCARE CORPORATION,

Defendants.

Civil Action No.: 05-349-GMS

BAXTER HEALTHCARE CORPORATION,

Counterclaimant,

v.

TALECRIS BIOTHERAPEUTICS, INC. and
BAYER HEALTHCARE LLC,

Counterdefendants.

ANSWER AND COUNTERCLAIM FOR DECLARATORY JUDGMENT

Baxter International Inc. ("BII") and Baxter Healthcare Corporation ("BHC") (collectively, "Baxter") hereby answer the Complaint filed by Talecris Biotherapeutics, Inc. ("Talecris") as follows:

NATURE OF THE ACTION

1. Baxter admits that Talecris filed a declaratory judgment action of infringement of United States Patent No. 6,686,191 ("the '191 patent") and that Plaintiff's action purports to arise under the patent laws of the United States. Except as specifically admitted, Baxter denies the allegations of paragraph 1.

THE PARTIES

2. Baxter is without sufficient information and belief to admit or deny the allegations in this paragraph and, on that basis, denies the allegations of paragraph 2.

3. Baxter admits the allegations of paragraph 3.

4. Baxter admits the allegations of paragraph 4.

5. Baxter admits the allegations of paragraph 5.

JURISDICTION AND VENUE

6. Baxter denies the allegations of paragraph 6.

7. Baxter admits the allegations of paragraph 7.

8. Baxter admits venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

THE '191 PATENT

9. Baxter admits that on its face the '191 patent is entitled "Preparation of Virally Inactivated Intravenously Injectable Immune Serum Globulin" and appears to have issued on February 3, 2004 based on an application filed by William R. Alonso. Baxter further admits that on its face the '191 patent appears to have been assigned to Bayer HealthCare LLC. Except as specifically admitted, Baxter denies the allegations of paragraph 9.

10. Baxter is without sufficient information or belief to admit or deny the allegation of paragraph 10 and on that basis denies the allegation of paragraph 10.

11. Baxter admits that the language of claims 1 and 23 are reflected in paragraph 11 of the Complaint. Except as specifically admitted, Baxter denies the allegations of paragraph 11.

12. Baxter is without sufficient information and belief to admit or deny and on that basis denies the allegations of paragraph 12.

FACTUAL ALLEGATIONS

13. Baxter admits that on April 27, 2005, the United States Food and Drug Administration (“FDA”) approved Baxter’s biologics license application for Immune Globulin Intravenous (Human), 10% Solution for manufacture and introduction or delivery into interstate commerce. Baxter further admits that the FDA advised that Baxter may label its product with the proprietary name “GAMMAGARD LIQUID.” Baxter also admits that a copy of the letter approving Baxter’s Biologic License Application (“BLA”) is attached to the Complaint as Exhibit A. Except as specifically admitted, Baxter denies the allegations of paragraph 13.

14. Baxter admits that the BLA for GAMMAGARD[®] LIQUID [Immune Globulin Intravenous (Human)] 10% (“GAMMAGARD LIQUID”) identifies BHC as the manufacturer. Baxter further admits that the April 27, 2005 letter approves the manufacture of GAMMAGARD LIQUID at Baxter’s Lessines, Belgium, facility. Except as specifically admitted, Baxter denies the allegations of paragraph 14.

15. Baxter admits that Baxter has publicly announced its intention to launch GAMMAGARD LIQUID in the fourth quarter of 2005. Baxter further admits that Exhibit B is a copy of a Baxter news release. Except as specifically admitted, Baxter denies the allegations of paragraph 15.

16. Baxter admits that it has begun or shortly intends to begin importing its GAMMAGARD LIQUID product for launch in the United States. Except as specifically admitted, Baxter denies the allegations of paragraph 16.

17. Baxter admits that the labeling information for GAMMAGARD LIQUID describes solvent/detergent treatment, 35 nm nanofiltration and low pH incubation at increased temperature. Except as specifically admitted, Baxter denies the allegations of paragraph 17.

18. Baxter denies the allegations of paragraph 18.

19. Baxter denies the allegations of paragraph 19.

FIRST CLAIM FOR RELIEF

**(DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '191 PATENT UNDER 35 U.S.C. § 271(G))**

20. Baxter realleges and incorporates herein its responses to paragraphs 1 through 19 above.

21. Baxter admits that Talecris purports to raise this count under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Except as specifically admitted, Baxter denies the allegations of paragraph 21.

22. Baxter denies the allegations of paragraph 22.

23. Baxter denies the allegations of paragraph 23.

24. Baxter denies the allegations of paragraph 24.

25. Baxter denies the allegations of paragraph 25.

26. Baxter denies the allegations of paragraph 26.

SECOND CLAIM FOR RELIEF

**(DECLARATORY JUDGMENT OF INFRINGEMENT
OF THE '191 PATENT UNDER 35 U.S.C. § 271(A))**

27. Baxter realleges and incorporates herein its responses to paragraphs 1 through 26 above.

28. Baxter admits that Talecris purports to raise this count under the

Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Except as specifically admitted, Baxter denies the allegations of paragraph 28.

29. Baxter denies the allegations of paragraph 29.

30. Baxter denies the allegations of paragraph 30.

31. Baxter denies the allegations of paragraph 31.

32. Baxter denies the allegations of paragraph 32.

THIRD CLAIM FOR RELIEF

(INDUCING INFRINGEMENT OF THE '191 PATENT UNDER 35 U.S.C. § 271(B))

33. Baxter realleges and incorporates herein its responses to paragraphs 1 through 32 above.

34. Baxter denies the allegations of paragraph 34.

35. Baxter denies the allegations of paragraph 35.

36. Baxter denies the allegations of paragraph 36.

AFFIRMATIVE DEFENSES

Answering further, Baxter raises the following affirmative defenses to the causes of action set forth in the Complaint.

FIRST AFFIRMATIVE DEFENSE

37. The complaint fails to allege facts sufficient to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

38. Talecris is barred from obtaining any relief sought in the Complaint because Baxter has not infringed and is not infringing, literally or equivalently, either directly or indirectly, any valid and enforceable claim of the '191 patent.

THIRD AFFIRMATIVE DEFENSE

39. Talecris is barred from obtaining any relief sought in the Complaint because the '191 patent, and each claim thereof, is invalid for failing to meet one or more of the conditions of patentability specified in 35 U.S.C. §§ 102, 103 and/or 112.

FOURTH AFFIRMATIVE DEFENSE

40. Talecris is barred from obtaining any relief sought in the Complaint by the doctrine of prosecution history estoppel, and Talecris is estopped from claiming that the '191 patent covers or includes the accused Baxter product.

FIFTH AFFIRMATIVE DEFENSE

41. Talecris is barred from obtaining any relief sought in the Complaint as it lacks standing because Bayer Healthcare LLC, the apparent owner of the '191 patent, did not join in filing this lawsuit. Upon information and belief, Bayer Healthcare LLC is the true owner of all pending patent applications and issued patents claiming priority to United States Patent Application No. 08/532,211, filed September 22, 1995, including the '191 patent and foreign counterparts.

COUNTERCLAIM

Baxter Healthcare Corporation ("BHC") counterclaims against Talecris and Bayer Healthcare LLC ("Bayer") as follows:

THE PARTIES

42. BHC is and at all relevant times has been a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.

43. Upon information and belief, Talecris is and at all relevant times has been

a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 4101 Research Commons, 79 TW Alexander Drive, Research Triangle Park, North Carolina 27709.

44. Upon information and belief, Bayer is and at all relevant times has been a limited liability company organized and existing under the laws of Delaware, with its principal place of business for its Biological Products division at 4101 Research Commons, 79 TW Alexander Drive, Research Triangle Park, North Carolina 27709.

JURISDICTION AND VENUE

45. This is a counterclaim for declaratory relief under the patent laws of the United States. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

46. This Court has jurisdiction over Talecris because it is a corporation organized and existing under the laws of the State of Delaware and because it has availed itself of this jurisdiction by filing the instant action. This Court also has jurisdiction over Bayer because it is a limited liability company organized and existing under the laws of Delaware and because, on information and belief, Bayer has purposefully conducted business in this judicial district.

47. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

THE CONTROVERSY

48. Upon information and belief, Talecris is a pharmaceutical company that has succeeded to Bayer's worldwide plasma products business.

49. Upon information and belief, Bayer is part of a worldwide pharmaceutical

company having different divisions, including a Biological Products division. Further upon information and belief, Bayer sold its worldwide plasma products business to NPS Biotherapeutics, a temporary holding company that became Talecris.

50. BHC is a biotechnology and medical products/services company that provides critical therapies for people with life-threatening conditions through three key businesses (BioScience, Medication Delivery and Renal Therapies). BHC therapies, products and services are used to treat patients with many conditions including cancer, trauma, hemophilia, immune deficiencies, kidney disease and other disorders. BHC's BioScience business provides therapeutic proteins derived from human plasma or recombinant technology to treat hemophilia, immune deficiencies and other blood-related disorders. The therapeutic product relevant to this action is BHC's intravenous immunoglobulin product GAMMAGARD LIQUID.

A. Intravenous Immunoglobulins

51. Persons suffering from a variety of conditions, including Kawasaki Syndrome, Chronic Lymphocytic Leukemia and Idiopathic Thrombocytopenic Purpura are lacking certain antibodies called immune globulins or immunoglobulins that help fight off infection. Immunoglobulin treatment can increase or provide the missing antibodies.

52. BHC manufactures and provides purified plasma treatments containing immunoglobulins that help patients with immune deficiency conditions fight off infection. For example, BHC manufactures GAMMAGARD S/D Immune Globulin Intravenous (Human), an effective, highly purified therapy used in treatments of autoimmune diseases. GAMMAGARD S/D is provided in powder form, so must be

reconstituted with sterile water prior to intravenous use. To facilitate the use of BHC's immunoglobulin treatment, BHC developed a new product, GAMMAGARD[®] LIQUID [Immune Globulin Intravenous (Human)] 10%, which is a ready-to-use, sterile preparation of highly purified and concentrated immunoglobulin G antibodies. GAMMAGARD LIQUID is manufactured in liquid form, rather than powder form, for ease of administration.

53. The controversy between BHC and Talecris/Bayer arises in relation to Baxter's GAMMAGARD LIQUID product. In particular, the present controversy relates to the specific processes by which BHC's GAMMAGARD LIQUID product is made as well as the resulting product itself.

B The '191 Patent

54. The United States application serial number 08/532,211 ("U.S. application"), which ultimately led to issuance of the '191 patent, was filed with the United States Patent Office on or about September 22, 1995. The claims in the U.S. application were pending before the Patent Office for almost nine years. The '191 patent issued on or about February 3, 2004. On information and belief, the '191 patent was assigned to Bayer.

FIRST CLAIM FOR RELIEF

**(DECLARATORY JUDGMENT OF NONINFRINGEMENT
OF THE '191 PATENT)**

55. BHC incorporates herein by reference Paragraphs 41 through 54 above.

56. An actual controversy has arisen and now exists between BHC on the one hand and Talecris and Bayer on the other hand with respect to BHC's noninfringement of any valid claims of the '191 patent. Talecris contends BHC, among others, infringes the

'191 patent. BHC contends that it does not infringe any valid claim of the '191 patent.

57. Pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination of the respective rights of the parties with respect to the noninfringement of the '191 patent is necessary and appropriate under the circumstances.

SECOND CLAIM FOR RELIEF

(DECLARATORY JUDGMENT OF INVALIDITY OF THE '191 PATENT)

58. BHC incorporates herein by reference Paragraphs 41 through 57 above.

59. An actual controversy has arisen and now exists between BHC on the one hand and Talecris and Bayer on the other hand with respect to the invalidity of the '191 patent. Talecris contends the '191 patent is valid. BHC contends that the '191 patent is invalid for failure to meet one or more of the conditions of patentability specified in 35 U.S.C. §§ 102, 103 and/or 112.

60. Pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination of the respective rights of the parties with respect to the validity of the '191 patent is necessary and appropriate under the circumstances.

PRAYER

WHEREFORE, Baxter International Inc. and Baxter Healthcare Corporation request entry of judgment in their favor and against Talecris Biotherapeutics, Inc. and Bayer Healthcare LLC as follows:

1. Holding that Talecris Biotherapeutics, Inc. take nothing by way of its Complaint;
2. Holding that Baxter Healthcare Corporation's GAMMAGARD[®] LIQUID [Immune Globulin Intravenous (Human)] 10% product does not infringe, either literally

or under the doctrine of equivalents, either directly or indirectly, any valid claim of U.S. Patent No. 6,686,191;

3. Declaring that Baxter Healthcare Corporation's GAMMAGARD[®] LIQUID [Immune Globulin Intravenous (Human)] 10% product does not infringe, either literally or under the doctrine of equivalents, either directly or indirectly, any valid claim of U.S. Patent No. 6,686,191;

4. Declaring the claims of United States Patent No. 6,686,191 are invalid;

5. Finding that this case be decreed an "exceptional case" within the meaning of 35 U.S.C. § 285 and reasonable attorney fees be awarded to Baxter International Inc. and Baxter Healthcare Corporation; and

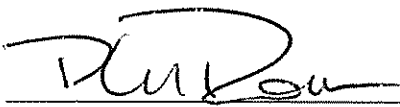
6. That Baxter International Inc. and Baxter Healthcare Corporation be awarded such other costs and further relief as the Court deems just and proper.

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Dated: August 31, 2005

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**IN THE UNITED STATES DISTRICT COURT
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CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on August 31, 2005, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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